General

Guideline Title

Anaphylaxis: assessment to confirm an anaphylactic episode and the decision to refer after emergency treatment for a suspected anaphylactic episode.

Bibliographic Source(s)

National Institute for Health and Clinical Excellence (NICE). Anaphylaxis: assessment to confirm an anaphylactic episode and the decision to refer after emergency treatment for a suspected anaphylactic episode. London (UK): National Institute for Health and Clinical Excellence (NICE); 2011 Dec. 25 p. (Clinical guideline; no. 134).

Guideline Status

This is the current release of the guideline.

Recommendations

Major Recommendations

Note from the National Guideline Clearinghouse (NGC): This guideline was developed by the Centre for Clinical Practice at the National Institute for Health and Clinical Excellence (NICE). See the "Availability of Companion Documents" field for the full version of this guidance.

Document the acute clinical features of the suspected anaphylactic reaction (rapidly developing, life-threatening problems involving the airway [pharyngeal or laryngeal oedema] and/or breathing [bronchospasm with tachypnoea] and/or circulation [hypotension and/or tachycardia] and, in most cases, associated skin and mucosal changes).

Record the time of onset of the reaction.

Record the circumstances immediately before the onset of symptoms to help to identify the possible trigger.

After a suspected anaphylactic reaction in adults or young people aged 16 years or older, take timed blood samples for mast cell tryptase testing as follows:

- A sample as soon as possible after emergency treatment has started
- A second sample ideally within 1–2 hours (but no later than 4 hours) from the onset of symptoms.

After a suspected anaphylactic reaction in children younger than 16 years, consider taking blood samples for mast cell tryptase testing as follows if the cause is thought to be venom-related, drug-related or idiopathic:

- A sample as soon as possible after emergency treatment has started

- A second sample ideally within 1–2 hours (but no later than 4 hours) from the onset of symptoms.

Inform the person (or, as appropriate, their parent and/or carer) that a blood sample may be required at follow-up with the specialist allergy service to measure baseline mast cell tryptase.

Adults and young people aged 16 years or older who have had emergency treatment for suspected anaphylaxis should be observed for 6–12 hours from the onset of symptoms, depending on their response to emergency treatment. In people with reactions that are controlled promptly and easily, a shorter observation period may be considered provided that they receive appropriate postreaction care prior to discharge.

Children younger than 16 years who have had emergency treatment for suspected anaphylaxis should be admitted to hospital under the care of a paediatric medical team.

After emergency treatment for suspected anaphylaxis, offer people a referral to a specialist allergy service (age-appropriate where possible) consisting of healthcare professionals with the skills and competencies necessary to accurately investigate, diagnose, monitor and provide ongoing management of, and patient education about, suspected anaphylaxis.

After emergency treatment for suspected anaphylaxis, offer people (or, as appropriate, their parent and/or carer) an appropriate adrenaline injector as an interim measure before the specialist allergy service appointment.

Before discharge a healthcare professional with the appropriate skills and competencies should offer people (or, as appropriate, their parent and/or carer) the following:

- Information about anaphylaxis, including the signs and symptoms of an anaphylactic reaction
- Information about the risk of a biphasic reaction
- Information on what to do if an anaphylactic reaction occurs (use the adrenaline injector and call emergency services)
- A demonstration of the correct use of the adrenaline injector and when to use it
- Advice about how to avoid the suspected trigger (if known)
- Information about the need for referral to a specialist allergy service and the referral process
- Information about patient support groups

Each hospital trust providing emergency treatment for suspected anaphylaxis should have separate referral pathways for suspected anaphylaxis in adults (and young people) and children.

Clinical Algorithm(s)

A care pathway for the management of anaphylaxis is provided in the full version of the original guideline document (see the "Availability of Companion Documents" field).

Scope

Disease/Condition(s)

Anaphylaxis

Guideline Category

Counseling

Evaluation

Management

Risk Assessment

Clinical Specialty

Allergy and Immunology

Emergency Medicine

Family Practice

Internal Medicine

Pediatrics

Intended Users

Advanced Practice Nurses

Hospitals

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To offer the best practice advice on the care of adults, young people and children following emergency treatment for suspected anaphylaxis

Target Population

Adults (age 18 and over), young people (age 16-18) and children (under age 16) in England and Wales who receive emergency treatment for suspected anaphylaxis in the National Health System

Interventions and Practices Considered

1. Documentation of:
    - Acute clinical features of the suspected anaphylactic reaction
    - Onset time
    - Circumstances prior to onset of symptoms
2. Blood samples for mast cell tryptase testing
3. Observation for 6-12 hours following symptom onset
4. Hospital admission (for children under 16)
5. Referral to specialist allergy service
6. Provision of adrenaline injector to patients/carers
7. Patient/carer education (anaphylaxis signs and symptoms, action to take for an anaphylactic reaction, adrenaline injector use, avoidance of triggers, patient support groups)
8. Separate referral pathways for adults (and young people) and children

Major Outcomes Considered

- Incidence of further or repeat anaphylactic episodes
- Rate of referral between healthcare settings
- Diagnostic utility of physical examination, history taking, serum mast tryptase measurement
- Admission rate for further anaphylactic episodes

- Mortality resulting from further anaphylactic episodes
- Health related quality of life
- Resource use and costs

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Note from the National Guideline Clearinghouse (NGC): This guideline was developed by the Centre for Clinical Practice at the National Institute for Health and Clinical Excellence (NICE). See the "Availability of Companion Documents" field for the full version of this guidance.

Search Strategies

The evidence reviews used to develop the guideline recommendations were underpinned by systematic literature searches, following the methods described in 'The guidelines manual' (2009) (see the "Availability of Companion Documents" field). The aim of the systematic searches was to comprehensively identify the published evidence to answer the review questions developed by the Guideline Development Group and Short Clinical Guidelines Technical Team.

The search strategies for the review questions were developed by the Information Services Team with advice from the Short Clinical Guidelines Technical Team. Structured questions were developed using the PICO (population, intervention, comparison, outcome) model and translated into search strategies using subject heading and free text terms. The strategies were run across a number of databases with no date restrictions imposed on the searches.

The National Health Service (NHS) Economic Evaluation Database (NHS EED) and the Health Economic Evaluations Database (HEED) were searched for economic evaluations. Search filters for economic evaluations and quality of life studies were used on bibliographic databases. There were no date restrictions imposed on the searches.

Guideline Development Group members were also asked to alert the Short Clinical Guidelines Technical Team to any additional evidence, published, unpublished or in press, that met the inclusion criteria.

The searches were undertaken between November 2010 and May 2011.

Scoping Searches

Scoping searches were undertaken in August 2010 using the following websites and databases (listed in alphabetical order); browsing or simple search strategies were employed. The search results were used to provide information for scope development and project planning.

Main Searches

The following sources were searched for the topics presented in the sections below.

- Clinical Trials.gov
- Current Controlled Trials
- Cochrane Database of Systematic Reviews – CDSR (Wiley)
- Cochrane Central Register of Controlled Trials – CENTRAL (Wiley)
- Database of Abstracts of Reviews of Effects – DARE (CRD)
- Health Technology Assessment Database – HTA (CRD)
- CINAHL (EBSCO)
- EMBASE (Ovid)
- MEDLINE (Ovid)
- MEDLINE In-Process (Ovid)
- National Research Register Archive

- UK Clinical Research Network

Inclusion and Exclusion Criteria

The following types of studies were included:

- Randomised or non-randomised controlled trials
- Observational studies reporting change to treatment plan or clinical outcome subsequent to intervention or testing
- Prognostic studies that have included a multivariable analysis (evaluating risk factors or signs in an analysis that includes other relevant factors or signs, rather than an unadjusted correlation)

The following study/publication types were excluded:

- Pre-clinical, animal studies
- Reviews, editorials, and opinion pieces
- Case reports
- Studies reporting only technical aspects of the test
- Studies with <20 participants

The searches of electronic searches yielded in 11,058 references. After screening of titles and abstracts, 10,951 references were excluded. The remaining 107 references were obtained and the full texts screened. Five studies were included with another 60 studies highlighted as possibly relevant for the background and/or the cost-effectiveness-analysis (CEA).

Cost-Effectiveness Analyses

A search strategy was designed in order to retrieve any economic evaluation or cost study in the population of allergy or anaphylaxis (refer to Appendix 1 of Appendix F of the full version of the guideline for how this was applied to each database). 40 papers were retrieved from title and abstract screening and 3 met the inclusion criteria for design and population. See Appendix F of the full version of the original guideline for details.

Number of Source Documents

Clinical: 5
Cost-effectiveness: 3

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Quality	Design
High	Randomised controlled trials (RCTs)
Low	Controlled observational studies
Very Low	Uncontrolled observational studies

Methods Used to Analyze the Evidence

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Note from the National Guideline Clearinghouse (NGC): This guideline was developed by the Centre for Clinical Practice at the National Institute

for Health and Clinical Excellence (NICE). See the "Availability of Companion Documents" field for the full version of this guidance.

A systematic review of clinical effectiveness (sections 3.1.2, 3.2.2, 3.4.2 and 3.5.2 of the full version of the guideline) was completed by NICE. A technical assessment report, which comprised of a systematic review of clinical and cost effectiveness with additional health-economic modelling (sections 3.3.2 and 3.3.4 of the full version of the guideline) was commissioned by NICE from Kleijnen Systematic Reviews Ltd, based in York, England. For full details of the technical assessment report, see Appendices F and G of the full version of the guideline.

When appropriate, GRADE (Grading of Recommendations Assessment, Development and Evaluation; see Appendix D of the full guideline document for details of the methods used) was applied to the studies.

Cost-Effectiveness Analysis (CEA)

Given the lack of CEA evidence, a cost-utility analysis was undertaken with costs and quality-adjusted life-years (QALY) considered over patients' lifetime from a United Kingdom (UK) National Health Service (NHS) perspective in accordance with NICE methods guidance. Costs were in 2011 Great Britain pounds sterling (£) and an annual discount rate of 3.5% was used. Despite these treatments being for short-term use, a lifetime horizon is most appropriate to capture the full impact of treatment.

Model Structure

A Markov model was constructed with mutually exclusive health states. The model simulated the course of events in a hypothetical cohort of persons with anaphylaxis who had been treated in an emergency care setting in the UK, aged 5 years or older. The model initially divides the cohort, according to their relative incidence (referred to as 'trigger probability'), into the four main causes of anaphylaxis, drugs (including medication, biologics, vaccines, and anaesthetics), insect (stings), food and idiopathic (see section on trigger probability in Appendix F of the full version of the guideline). In the model, as time progresses, persons move from one state to another state according to a set of transition probabilities (see sections on model parameters: rate of recurrence, mortality rates, idiopathic treatment and venom immunotherapy, paragraphs; 2.4.2, 2.4.4-2.4.6 in Appendix F of the full version of the guideline). The cycle length of the model was set to three months.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Note from the National Guideline Clearinghouse (NGC): This guideline was developed by the Centre for Clinical Practice at the National Institute for Health and Clinical Excellence (NICE). See the "Availability of Companion Documents" field for the full version of this guidance.

Forming and Running the Short Clinical Guideline Development Group (GDG)

Each short clinical guideline is developed by a unique GDG consisting of 10–12 members, supported by the Short Clinical Guidelines Team. Each GDG has a Chair, healthcare professional members and a minimum of two patient and carer members. Co-opted expert advisers are recruited, as appropriate. A Clinical Adviser, who has specific content expertise and additional responsibilities, may also be appointed depending on the topic. Recruitment of the GDG Chair and members is carried out in accordance with NICE's policy.

The GDG makes its decisions using the best available evidence presented to it at GDG meetings by the Short Clinical Guidelines Team. The use of formal consensus methods within the GDG will be considered on a case-by-case basis.

Developing Review Questions

A short clinical guideline has a narrow scope and covers only part of a care pathway. It addresses a maximum of three subject areas covering clinical management. This will result in a small number of key clinical issues. These are broken down into a defined number of review questions — usually one or two per clinical management area. The exact number will be dictated by the size of the short clinical guideline remit and the amount of development time available.

Creating Guideline Recommendations

Explicit methods of linking the evidence to recommendations are used for short clinical guidelines if the topic is suitable. This involves using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach.

Research recommendations are formulated for short clinical guidelines. Their number is dependent on the size of the short clinical guideline remit and the amount of development time available.

Writing the Guideline

There are usually three versions of short clinical guidelines:

- The full guideline – all the recommendations, details of how they were developed and summaries of the evidence they are based on.
- The quick reference guide – a summary of the recommendations for healthcare professionals.
- 'Understanding NICE guidance' – a summary for patients and carers.

The full guideline is written by the Short Clinical Guidelines Team, following the principles in chapters 9 and 10 of 'The guidelines manual' (see the "Availability of Companion Documents" field).

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

Anaphylaxis is a life-threatening condition that can be caused by a number of different triggers, the main ones being food, insect and drug, but with a large percentage of cases being idiopathic. Both UK and international guidelines recommend both referral to specialist service (SS) for elucidation of trigger and management and prescription of adrenaline injectors (AIs) in case of recurrence. The purpose of this study was to estimate the cost effectiveness of SS and AIs compared to standard care (SC) (no referral to specialist service) and no AI prescription. Therefore, a Markov type model was constructed, according to best practice, to simulate the natural history and various care pathways for each of the triggers in order to estimate the lifetime National Health Service (NHS) cost and quality-adjusted life years (QALYs) for each of the comparators (SS plus AI, SS no AI, SC plus AI, SC no AI). Evidence to inform model parameters was obtained as systematically as possible, using expert opinion either to validate or provide estimates. Results of the cost analysis showed that both standard care (SC) strategies (no referral to specialist service [SS] and no adrenaline injector [AI] prescription) were dominated (less effective and more costly than SS) and that the incremental cost-effectiveness ratio (ICER) for SS plus AI was £1800 with a probability of being cost effective of at least 50% above an ICER threshold of about £2000. This was shown to be robust to extensive sensitivity analysis.

See Appendix F of the full-length guideline document for details of the cost-effectiveness analysis.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

The guideline was validated through two consultations.

1. The first draft of the guideline (the full guideline, National Institute for Health and Clinical Excellence [NICE] guideline, and Quick Reference Guide) were consulted with Stakeholders and comments were considered by the Guideline Development Group (GDG).
2. The final consultation draft of the Full guideline, the NICE guideline and the Information for the Public were submitted to stakeholders for final comments.

The final draft was submitted to the Guideline Review Panel for review prior to publication.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is not specifically stated for each recommendation.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate management and referral of patients who experience anaphylaxis

Potential Harms

- False positive or false negative results from mast cell tryptase measurements
- Potentially premature discharge from hospital observation
- Potential anxiety associated with an incorrect diagnosis of and referral for anaphylaxis
- Potential adverse effect from inappropriate use of an adrenaline injector, such as in patients with cardiac problems or children prescribed an inappropriate dose

Qualifying Statements

Qualifying Statements

- This guidance represents the view of the National Institute of Health and Clinical Excellence (NICE), which was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer, and informed by the summary of product characteristics of any drugs they are considering.
- Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.

Implementation of the Guideline

Description of Implementation Strategy

The National Institute for Health and Clinical Excellence (NICE) has developed tools to help organisations implement this guidance (see http://guidance.nice.org.uk/CG134 ; see also the "Availability of Companion Documents" field).

Implementation Tools

Audit Criteria/Indicators

Chart Documentation/Checklists/Forms

Clinical Algorithm

Patient Resources

Resources

Slide Presentation

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

National Institute for Health and Clinical Excellence (NICE). Anaphylaxis: assessment to confirm an anaphylactic episode and the decision to refer after emergency treatment for a suspected anaphylactic episode. London (UK): National Institute for Health and Clinical Excellence (NICE); 2011 Dec. 25 p. (Clinical guideline; no. 134).

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2011 Dec

Guideline Developer(s)

National Institute for Health and Care Excellence (NICE) - National Government Agency [Non-U.S.]

Source(s) of Funding

National Institute for Health and Clinical Excellence (NICE)

Guideline Committee

Guideline Development Group

Composition of Group That Authored the Guideline

Guideline Development Group (GDG) Members: Peter Howdle (GDG Chair), Emeritus Professor of Clinical Medicine, University of Leeds; Trevor Brown ,Consultant Paediatric Allergist (secondary care), The Children's Allergy Service, The Ulster Hospital, Northern Ireland; Sue Clarke, Clinical Lead/Lecturer in Allergy and Paediatric Asthma, Education for Health, Warwick; Matthew Doyle, GP Partner, Cromwell Place Surgery, St Ives; Mandy East, Patient representative, The Anaphylaxis Campaign; Pamela Ewan, Consultant Allergist, Associate Lecturer and Head of Allergy Department, Cambridge University Hospitals NHS Foundation Trust and University of Cambridge Clinical School; David Glaser, Patient member; Nigel Harper, Consultant Anaesthetist, Central Manchester University Hospitals NHS Foundation Trust; Prashant Kumar, Consultant Paediatrician, Sunderland Royal Hospital Nicola Mundy, Patient member

Financial Disclosures/Conflicts of Interest

For the declarations of interests of all the contributors to this guideline, see Appendix A in the full version of the original guideline.

Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site .

Availability of Companion Documents

The following are available:

- Anaphylaxis: assessment to confirm an anaphylactic episode and the decision to refer after emergency treatment for a suspected anaphylactic episode. Full Guideline. London (UK): National Institute for Health and Clinical Excellence (NICE); 2011 Dec. 25 p. (Clinical guideline; no. 134). Electronic copies: Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site .
- Anaphylaxis: assessment to confirm an anaphylactic episode and the decision to refer after emergency treatment for a suspected anaphylactic episode. Appendices C and D. London (UK): National Institute for Health and Clinical Excellence (NICE); 2011 Dec. 82 p. (Clinical guideline; no. 134). Electronic copies: Available in PDF from the NICE Web site .
- Anaphylaxis: assessment to confirm an anaphylactic episode and the decision to refer after emergency treatment for a suspected anaphylactic episode. Appendix E. London (UK): National Institute for Health and Clinical Excellence (NICE); 2011 Dec. 65 p. (Clinical guideline; no. 134). Electronic copies: Available in PDF from the NICE Web site .
- Anaphylaxis: assessment to confirm an anaphylactic episode and the decision to refer after emergency treatment for a suspected anaphylactic episode. Appendix F. London (UK): National Institute for Health and Clinical Excellence (NICE); 2011 Dec. 137 p. (Clinical guideline; no. 134). Electronic copies: Available in PDF from the NICE Web site .
- Anaphylaxis: assessment to confirm an anaphylactic episode and the decision to refer after emergency treatment for a suspected anaphylactic episode. Appendix G. London (UK): National Institute for Health and Clinical Excellence (NICE); 2011 Dec. 65 p. (Clinical guideline; no. 134). Electronic copies: Available in PDF from the NICE Web site .
- Anaphylaxis: baseline assessment. Implementing NICE Guidance. Baseline assessment tool. London (UK): National Institute for Health and Clinical Excellence (NICE); 2011 Dec. 14 p. (Clinical guideline; no. 134). Electronic copies: Available from the NICE Web site .
- Anaphylaxis. Clinical audit tool. London (UK): National Institute for Health and Clinical Excellence (NICE); 2011 Dec. 9 p. (Clinical

guideline; no. 134). Electronic copies: Available from the NICE Web site .

- Anaphylaxis: assessment to confirm an anaphylactic episode and the decision to refer after emergency treatment for a suspected anaphylactic episode. Costing statement. London (UK): National Institute for Health and Clinical Excellence (NICE); 2011 Dec. 9 p. (Clinical guideline; no. 134). Electronic copies: Available in PDF from the NICE Web site .
- Anaphylaxis. Electronic audit tool. London (UK): National Institute for Health and Clinical Excellence (NICE); 2011 Dec. 9 p. (Clinical guideline; no. 134). Electronic copies: Available from the NICE Web site .
- Anaphylaxis: assessment and referral. Slide set. London (UK): National Institute for Health and Clinical Excellence (NICE); 2011 Dec. 18 p. (Clinical guideline; no. 134). Electronic copies: Available from the NICE Web site .
- NICE pathways. Anaphylaxis overview. London (UK): National Institute for Health and Clinical Excellence (NICE); 2011. Various pages. Available from the NICE Web site .
- The guidelines manual 2009. London (UK): National Institute for Health and Clinical Excellence (NICE); 2009 Jan. Electronic copies: Available from the NICE Archive Web site .

Patient Resources

The following is available:

- Anaphylaxis. Understanding NICE guidance. Information for people who use NHS services. London (UK): National Institute for Health and Clinical Excellence (NICE); 2011 Dec. 8 p. (Clinical guideline; no. 134). Electronic copies: Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site .

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC Status

This NGC summary was completed by ECRI Institute on June 18, 2012.

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